K071851

HDC
Health Development Company

OCT 18 2007

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant: HDC s.r.l
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36060 – SARCEDO (Vicenza) - Italy
Tel: +39 0445 364148
Fax: +39 0445 383645

Contact Person: Marco Benvegnù

Alternate Contact Person: Guido Bonapace (consultant)
ISENET
Via Calindri, 50
40068 - San Lazzaro di Savena (Bologna) - Italy
Tel: +39 051 6257315
Fax: +39 051 6284344
Email: gbonapace@alice.it

Date: October 17, 2007

Device Name
Proprietary Name : HDC Sterile Spider Screw

Common/Usual Name: Bone Screw

Classification Names: Endosseous dental implant

Device Classification: Class II, 21 CFR 872.3640, Product Code DZE

510 K Number	Device Trade Name	Manufacturer
K052471	Spider Screw	HDC
K062733	Tomas-pin	Dentaurum
K033767	Dual Top Anchor System	Jeil Medical

Device Description:

The HDC Sterile Spider Screw is a titanium fixation device to be inserted into the upper or lower jaws, designed to be immediately used (after the bone insertion) as fixation for orthodontic appliances. It is used temporarily and must be removed after the orthodontic treatment has been completed. It is provided sterile and is intended for single use only. The Sterile Spider Screw is provided in two configuration "Self Tapping" and "Self Drilling and Self Tapping." Self Tapping Spider Screw is manufactured from ASTM F67 and ASTM F136. Self Drilling and Self Tapping Spider Screw is manufactured from ASTM F136. HDC Sterile Spider Screw is provided in three tip size diameters: 1.3 mm, 1.5 mm and 2.0 mm.

Basis of Substantial Equivalence:

HDC Spider Screws are similiar to predicate devices in intended use, material, design, and function. The intended use is identical to K052471 and K062733.
The design is substantially equivalent to K052471 and K062733.
The anchorage system of the PIN model is substantially equivalent to the K033767.

Intended Use:

The HDC Sterile Spider Screw is a threaded titanium dental implant screw, intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and must be removed after the orthodontic treatment has been completed. It is provided sterile and is intended for single use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

HDC s.r.l
C/O Mr. Guido Bonapace
Consultant
ISENET
Via Calindri, 50
San Lazzaro di Savena, Bologna
ITALY 40068

Re: K071851
Trade/Device Name: HDC, Sterile Spider Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: OAT
Dated: September 27, 2007
Received: October 9, 2007

Dear Mr. Bonapace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

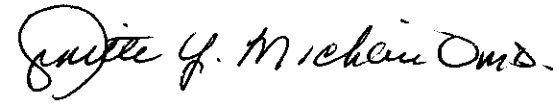
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K071851

Device Name: HDC, Sterile Spider Screw

Indications for Use:

The HDC Sterile Spider Screw is a threaded titanium dental implant screw, intended to serve as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of the teeth. It is used temporarily and must be removed after the orthodontic treatment has been completed. It is provided sterile and is intended for single use only.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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